IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF PUERTO RICO

UNITED STATES OF AMERICA,

Plaintiff,

v.

Criminal No.07-075(CCC)

[6] RUBEN OTERO-LOPEZ,

Defendant.

PLEA AGREEMENT

TO THE HONORABLE COURT:

COMES NOW the United States of America, by and through its attorneys, Rosa Emilian Rodríguez-Vélez, United States Attorney for the District of Puerto Rico, José A. Ruiz-Santiago, Assistant U.S. Attorney, Chief, Criminal Division, and Julia Díaz-Rex, Assistant United States Attorney, for said District and the defendant, [6] RUBEN OTERO-LOPEZ, and the defendant's counsel, Teodoro Méndez-Lebrón, Esq., pursuant to Rule 11(c)(1)(A) and (B) of the Federal Rules of Criminal Procedure, and state to this Honorable Court, that they have reached an agreement, the terms and conditions of which are as follows:



1. COUNT TO WHICH DEFENDANT PLEADS GUILTY

The defendant agrees to plead guilty to COUNT ONE of the Indictment pending against him, charging him engaging in a conspiracy to defraud the United States, in violation of Title 18, United States Code, Section 371.

2. MAXIMUM PENALTIES

The maximum penalty for the offense charged in COUNT ONE of the indictment is a term of imprisonment of not more than five (5) years and/or a fine of not more than \$500,000, plus a term

of supervised release of not more than three (3) years in addition to any term of incarceration, and a special assessment of one hundred dollars (\$100.00) per count, as required by Title 18, <u>United</u> States Code, Section 3013(a).

3. FINES AND/OR RESTITUTION

The Court may, pursuant to Section 5E1.2(I) of the <u>Sentencing Guidelines</u>, <u>Policy Statements</u>, <u>Application</u>, and <u>Background Notes</u>, order the defendant to pay a fine sufficient to reimburse the government for the costs of any imprisonment and/or supervised release ordered and also the Court may impose restitution. The defendant agrees to execute a financial statement to the United States (OBD Form 500). The United States will make no recommendations as to the imposition of fines.

4. **RULE 11(c)(1)(B) WARNINGS**

The defendant is aware that the defendant's sentence is within the sound discretion of the sentencing judge, but the same may be imposed following the <u>United States Sentencing Guidelines</u>. Policy Statements, Application, and Background Notes as advisory to the imposition of sentence. The defendant is aware that the Court has jurisdiction and authority to impose any sentence within the statutory maximum set for the offense to which the defendant pleads guilty. If the Court should impose a sentence up to the maximum established by statute, the defendant cannot, for that reason alone, withdraw a guilty plea, and will remain bound to fulfill all of the obligations under this plea agreement.



5. ADVISORY NATURE OF THE SENTENCING GUIDELINES

The defendant is aware that pursuant to the decisions issued on January 12, 2005, by the Supreme Court of the United States in the cases of <u>United States v. Booker</u> and <u>United States v. Fanfan</u>, 125 S.Ct. 738, 2005 WL 50108 (January 12, 2005), the Sentencing Guidelines are no longer mandatory and must be considered effectively advisory.

6. SENTENCING GUIDELINE CALCULATIONS

The United States and the defendant agree that the following Sentencing Guidelines calculations apply to the defendant's conduct with regard to COUNT ONE of the indictment:

BASE OFFENSE LEVEL [USSG § 2N2.1 and § 2B1.1] 6		
Specific Offense Characteristics	More than \$10,000 but less than \$30,000 [§ 2B1.1(b)(1)(D)] (Defendant to be held accountable for the amounts he personally gained, which is more than \$10,000 but less than \$30,000.)	+4
	The offense involved 10 or more victims or was committed through mass-marketing. [§ 2B1.1(b)(2)(A)]	+2
Role in Offense	Abuse of position of trust. [§3B1.3]	+2
	Open issue: the defendant will argue for a two (2) level downward adjustment for role in the offense; the Government will argue that defendant was not a minor participant.	-2 or +0
Acceptance of Responsibility [USSG § 3E1.1]		-2
TOTAL OFFENSE LEVEL		10 or 12
TOTAL Imprisonment Range @ Criminal History Category 'I'		6-2, Zone B 10-16, Zone C

7. SPECIFIC SENTENCE RECOMMENDATION

Should the Court find that defendant's total offense level is '10', the Government would recommend a sentence of 3 years probation with conditions of home detention for the first 6 months.





Should the Court find that defendant's total offense level is '12', the Government would recommend a 10-month split sentence, that is, 5 months of imprisonment followed by a term of supervised release that includes home detention or community confinement during the first 5 months of the supervised release term. These recommendations are subject to defendant possessing a Criminal History Category (CHC) of 'I'. Should the defendant possess a CHC greater than one, the parties recommend a sentence of imprisonment at the lower end of the applicable guideline.

8. NO FURTHER ADJUSTMENTS OR DEPARTURES

The United States and the defendant agree that no further adjustments or departures to the defendant's total offense level shall be sought by the parties.

9. NO STIPULATION AS TO CRIMINAL HISTORY CATEGORY

The parties do not stipulate any assessment as to the defendant's Criminal History Category.

10. UNITED STATES' RESERVATION OF RIGHTS

The United States reserves the right to carry out its responsibilities under guidelines sentencing. Specifically, the United States reserves the right: (a) to bring its version of the facts of this case including its file and any investigative files to the attention of the probation office in connection with that office's preparation of a presentence report; (b) to dispute sentencing factors or facts material to sentencing; and, (c) to seek resolution of such factors or facts in conference with opposing counsel and the probation office.

11. SATISFACTION WITH COUNSEL

The defendant represents to the Court to be satisfied with counsel, Teodoro Méndez-Lebrón, Esq., and indicates that counsel has rendered effective legal assistance.

12. RIGHTS SURRENDERED BY DEFENDANT THROUGH GUILTY PLEA

Defendant understands that by entering into this agreement, defendant surrenders certain rights as provided in this agreement. Defendant understands that the right of criminal defendants include the following:

- a. If the defendant had persisted in a plea of not guilty to the charges, defendant would have the right to a speedy jury trial with the assistance of counsel. The trial may be conducted by a judge sitting without a jury if the defendant, the United States and the judge agree.
- b. If a jury trial is conducted, the jury would be composed of twelve lay persons selected at random. The defendant and defendant's attorney would assist in selecting the jurors by removing prospective jurors for cause where actual bias or other disqualification is shown, or by removing prospective jurors without cause by exercising peremptory challenges. The jury would have to agree, unanimously, before it could return a verdict of either guilty or not guilty. The jury would be instructed that the defendant is presumed innocent, that it could not convict the defendant unless, after hearing all the evidence, it was persuaded of the defendant's guilt beyond a reasonable doubt, and that it was to consider each charge separately.
- c. If a trial is held by the judge without a jury, the judge would find the facts and, after hearing all the evidence and considering each count separately, determine whether or not the evidence established the defendant's guilt beyond a reasonable doubt.
- d. At a trial, the United States would be required to present its witnesses and other evidence against the defendant. The defendant would be able to confront those witnesses and defendant's attorney would be able to cross-examine them. In turn, the defendant could present



witnesses and other evidence in defendant's own behalf. If the witnesses for the defendant would not appear voluntarily, defendant could require their attendance through the subpoena power of the Court.

e. At a trial, the defendant could rely on the privilege against self-incrimination to decline to testify, and no inference of guilty could be drawn from his refusal to testify. If the defendant desired to do so, the defendant could testify in his own behalf.

13. STATEMENT OF FACTS

The accompanying Statement of Facts signed by the defendant is hereby incorporated into this plea agreement. Defendant adopts the Statement of Facts and agrees that the facts therein are accurate in every respect and, had the matter proceeded to trial, that the United States would have proven those facts beyond a reasonable doubt.

14. LIMITATIONS OF PLEA AGREEMENT

This plea agreement binds only the United States Attorney's Office for the District of Puerto Rico and the defendant; it does not bind any other federal district, state or local authorities. Furthermore, the defendant is fully aware that the Court is not bound by this plea agreement, including but not limited as to: advisory sentencing guidelines calculations, stipulations, and/or sentence recommendations.

15. ENTIRETY OF PLEA AGREEMENT

This written agreement constitutes the complete plea agreement between the United States, the defendant, and the defendant's counsel. The United States has made no promises or representations except as set forth in writing in this plea agreement and deny the existence of any other term and conditions not stated herein.

16. AMENDMENTS TO PLEA AGREEMENT

No other promises, terms or conditions will be entered unless in writing and signed by all parties.

17. WAIVER OF APPEAL

The defendant hereby agrees that if this Honorable Court accepts this Plea Agreement and sentences him/her according to its terms, conditions, and recommendations, the defendant waives and surrenders his right to appeal the judgment and sentence in this case.

18. VOLUNTARINESS OF GUILTY PLEA

The defendant acknowledges that no threats have been made against the defendant and that the defendant is pleading guilty freely and voluntarily because the defendant is guilty.

RESPECTFULLY SUBMITTED.

ROSA EMILIA RODRIGUEZ-VELEZ United States Attorney

José A. Ruiz Santiago Assistant U.S. Attorney

Chief, Criminal Division

Dated: 9/20/07

Rubén Otero-Lópe

Defendant

Dated:

Teodoro Méndez-Lebrón

Counsel for Defendant

Dated: 🕈

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I have consulted with my counsel and fully understand all my rights with respect to the Indictment pending against me. Further, I have consulted with my attorney and fully understand my rights with respect to the provision of the Sentencing Guidelines, Policy Statements, Application, and Background Notes which may apply in my case. I have read this plea agreement and carefully reviewed every part of it with my attorneys. I fully understand this agreement and I voluntarily agree to it.

Date: 09/20/07

Rubén Otero-López

Defendant

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I am the attorney for the defendant. I have fully explained to the defendant his rights with respect to the pending Indictment. Further, I have reviewed the provisions of the Sentencing Guidelines, Policy Statements, Application, and Background Notes, and have fully explained to the defendant the provisions of those guidelines which may apply in this case. I have also explained to the defendant the advisory nature of the Sentencing Guidelines. I have carefully reviewed every part this plea and agreement with the defendant. To my knowledge, the defendant is entering into this agreement is voluntarily, intelligently and with full knowledge of all the consequences of his plea of guilty.

Date: 9/20/07

eodoro Méndez-Lebrón, É

Counsel for Defendant

GOVERNMENT'S VERSION OF THE FACTS

In conjunction with the submission of the accompanying plea agreement in this case, the United States of America submits the following statement setting forth the United States' version of the facts leading to the defendant's acceptance of criminal responsibility for Count One of the indictment.

Pharma Blood was a business that advertised, marketed and distributed a cancer treatment for cancer patients by way of the "Pharma Blood Cancer Vaccination" (PCV), an autologous hemoderivative cancer immunotherapy. PCV was a drug that was not approved for use in humans in the United States by the FDA. From mid-June 2003 to June 24, 2004, the PCV was made available to the general public at Pharma Blood Cancer Center, as San Juan Bautista Hospital, in Caguas, Puerto Rico.

Pharma Blood, Inc. was a profit corporation organized under the laws of the State of Florida on April 23, 2002, and duly authorized to do business in Puerto Rico since January 28, 2004. Pharma Blood Medical Center, Inc. was a profit corporation organized under the laws of the Commonwealth of Puerto Rico on or about March 21, 2003. Pharmablood Medical Center, Inc. possessed bank accounts at Banco Bilbao Viscaya and Doral Bank, both financial institutions whose deposits were insured by the Federal Deposit Insurance Corporation. Pharma Blood Research Corporation was a non-profit corporation organized under the laws of the Commonwealth of Puerto Rico on August 18, 2003.



From on or about March 2003 and continuing through to on or about June 24, 2004, in the District of Puerto Rico and elsewhere, and within the jurisdiction of this Court, defendant [6] RUBEN OTERO-LOPEZ knowingly and willfully agreed with others to unlawfully market and distribute in interstate commerce the PCV, a drug that was not approved for use in human beings in the United States by the federal Food and Drug Administration, for personal gain and profit, for the purpose of impairing, obstructing and defeating the lawful function of said agency of the United States.

During the time of the conspiracy defendant [6] RUBEN OTERO-LOPEZ failed to exercise due diligence in informing himself of the legal requirements to marketing, advertising and distributing the PCV in the United States.

Defendant RUBEN OTERO-LOPEZ was a physician licensed to practice medicine in Puerto Rico. From mid-June 2003 until sometime in April 2004, defendant OTERO served as a physician for Pharma Blood Cancer Center.

On or about September 2, 2003, defendant [6] RUBEN OTERO-LOPEZ signed a letter addressed to Dr. Martin Dayton, that provided details of the PCV that was to be administered by Dayton to a female patient in Miami Beach, Florida. This letter was signed by defendant although the signature block read: "Eduardo Lasalvia-Prisco MD". The PCV for the female patient processed at Pharma Blood Cancer Center, in Caguas, Puerto Rico, and was subsequently delivered through private mail carrier from Puerto Rico to Miami Beach.

On October 13, 2003, defendants COTTO, OTERO and CUCCHI appeared in a Channel 2 television news broadcast describing Pharma Blood's Cancer Vaccination.

On or about November 20, 2003, defendant ALBERTINI faxed a letter from Pharma Blood's offices in North Miami, to defendant COTTO in Puerto Rico, where ALBERTINI warned COTTO that FDA regulations prohibited the dissemination of information to the public about treatments and drugs not approved by FDA. COTTO claims that he never saw or read this fax letter. However, FDA agents seized this faxed letter from the premises of Pharma Blood's Cancer Center in Hospital San Juan Bautista during the execution of a federal search warrant there on December 2, 2003.

On or about December 4, 2003, defendants LASALVIA and OTERO appeared in a Channel 4 television news report aired that day announcing the Pharma Blood Cancer Vaccination to the general public and that showed the injecting of a patient with the vaccine; this news report aired two (2) days after a federal search warrant was executed upon the premises of Pharma Blood's treatment center in San Juan Bautista Hospital.

On or about March 3, 2004, defendant ALBERTINI requested an Investigational New Drug Exemption and submitted an Investigational New Drug Application (INDA) for Pharma Blood's vaccine from the FDA's Office of Blood Research and Review, where she listed defendant LASALVIA as the lead investigator and defendants CUCCHI and OTERO as assistant investigators, and where defendant ALBERTINI agreed not to begin clinical investigations until thirty (30) days after FDA's receipt of the INDA unless she received earlier notification by FDA that the studies may begin, and where defendant ALBERTINI further agreed not to begin or continue clinical investigations covered by the INDA if those studies were placed on clinical hold. Defendant OTERO has stated that he was unaware of this application and his purported role as investigator.

Despite the representations made by defendant ALBERTINI to the FDA mentioned in the preceding paragraph, between on or about March 4, 2004 and April 7, 2004, persons associated to Pharma Blood continued to market and inject the non-approved vaccine into human beings in its Treatment Center in Caguas, Puerto Rico and continued to charge patients for said vaccine. During this time defendants LASALVIA and OTERO evaluated individuals for Pharma Blood's treatment and defendant COTTO provided information to individuals regarding Pharma Blood's treatment.

Full discovery has been provided to defense.

José A. Ruiz-Santiago

Assistant U.S. Attorney Chief, Criminal Division

Dated: 9/ 30/0구

Rubén Otero-López

Defendant

Dated:

Teodoro Méndez-Lebrón, Esq

Counsel for Defendant

Dated: 9-20-07